EXHIBIT 169

From: Barbarite, Joseph
Sent: Thursday, May 13, 2010 12:36 PM
To: Feniger, Angela; Donato, Lou; Karaban, Dino
Cc: Surapanaene, Ramu; Davenport, Robert; Polke, Robert; Guacci, Anthony; Abrahamson, Yvette
Subject: FW: Review Report
Attachments: Par_Pharmaceutical_Report-fnl.pdf

Importance: High

Attached is the audit report from our DEA consultants. Take a close read of it, assign a priority level to the observations and develop timelines for corrective actions. Note corrective actions for the critical items should be started immediately. I will schedule a meeting for after I get back from China so you can present our timelines for the improvements.

Joseph A. Barbarite| Vice President Quality and Compliance
Par Pharmaceutical Companies, Inc. | One Ram Ridge Rd | Spring Valley, N.Y. 10977
Phone: [redacted] Joseph.Barbarite@parpharm.com
www.parpharm.com

From: PROFFITT Joy [mailto:Joy.Proffitt@cegedim.com]
Sent: Wednesday, May 12, 2010 11:20 AM
To: Barbarite, Joseph
Cc: WILLIAMSON Robert; HAMBY Paul
Subject: Review Report
Importance: High

Dear Mr. Barbarite,

Attached please find the report for the high level review of Par Pharmaceutical's handling of control substances. This report has been prepared for you by Patricia Van Nostrand and John Buckley, Senior Associates, of our organization.

A hard copy of this report will be sent to your attention today via US Mail.

Please let us know if you have any questions.

Thank you,

Joy L. PROFFITT | Administrative Assistant
Cegedim Dendrite | 1025 Boulders Parkway, Suite 405, Richmond VA 23225
Tel: 804-230-5044 | Fax: 804-267-1746 | email: joy.proffitt@cegedim.com

cegedim dendrite

cegedim dendrite

Compliance Solutions
powered by BuzzeoPDMA

Via Mail and Email: Joseph.Barbarite@parpharm.com

May 8, 2010

Joseph Barbarite
Vice President, Quality Assurance & Compliance
Par Pharmaceutical
One Ram Ridge Road
Spring Valley, NY 10977

Dear Mr. Barbarite:

Please find enclosed a report prepared by Senior Associates Patricia Van Nostrand and John Buckley pertaining to their "high level" review of Par Pharmaceutical's handling of controlled substances. The review disclosed regulatory issues related to the use of Order Forms, improper importation documentation and other technical issues related to the maintenance of multiple Drug Enforcement Administration registrations in numerous facility locations. Regulatory findings are noted along with Code of Federal Regulation citations when applicable.

Please advise if you require further information and/or clarification and if we could provide assistance with an on-site resource and/or follow-up to assist in the implementation of our recommendations. .

Sincerely,

Ron Buzzeo

Ronald W. Buzzeo, RPh
Chief Compliance Officer

RWB:adm
Attachment: Report
Excel Charts

PAR PHARMACEUTICAL
[redacted]

EXECUTIVE SUMMARY

On April 20 - 22, 2010, Patricia Van Nostrand and John Buckley, Senior Associates with Cegedim Dendrite Compliance Solutions powered by BuzzeoPDMA (CDCS) visited the Par Pharmaceutical (Par) [redacted] to conduct a limited Drug Enforcement Administration (DEA) type compliance review. The on-site time was limited to three days resulting in a "high level" review. The review included controlled substance physical and operational security, controlled substance procedures, record keeping, inventories, employee screening practices and DEA required reporting.

The [redacted] facility procures bulk Schedule IIIN and Schedule IV active drug substances for the manufacture of dosage forms. Additionally, Schedule II activities have been initiated for research and development purposes with anticipated Food and Drug Administration (FDA) filing and approval for commercial manufacturing. The layout of the facility at [redacted] includes four buildings, spread out between streets and other businesses. There are eight DEA registrations for manufacturing, import, export, analytical laboratory and distribution. The focus of this review was to provide an overview of the regulatory requirements encompassed by all registrations and buildings, including distribution, which is located in [redacted]

The last DEA inspection was in July 2009. It was stated that no issues were discovered by the DEA.

A closeout meeting was held on April 22, 2010 with Joseph Barbarite, Vice President QA and Compliance; Dino Karaban, Senior Director, QA Compliance; Bob Davenport, Director Quality Assurance Operations; Bob Polk, Vice President, Manufacturing and Tech Operations; Angela Feniger, Associate Director, Technical Writing and Documentation; and Louis Donato, Associate Director of Compliance, to discuss the review findings.

The following report provides Findings and Recommendations. Citations are provided where applicable.

FINDINGS AND RECOMMENDATIONS:

Finding No. 1:

DEA Forms 222 are not being filled out correctly. In one instance, the size of the package was written as the strength of the product being ordered and not the bottle count. Additionally, when Oxycodone HCl was being ordered, it was written only as

Oxycodone, which would be construed as Oxycodone Base. In addition, some executed DEA Forms were not forwarded to the DEA.

Requirement: 21 CFR 1305.12 Procedure for executing DEA Forms 222

(b) Only one item may be entered on each numbered line. An item must consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance. The number of lines completed must be noted on that form at the bottom of the form, in the space provided. DEA Forms 222 for carfentanil, etorphine hydrochloride, and diprenorphine must contain only these substances

Recommendation:

The requirements in the Code of Federal Regulations for using DEA Forms 222 should be reviewed and incorporated into a DEA training program. An SOP does describe some detail on using these forms; however it is recommended that an SOP specifically on how to fill out and use these forms should be written with enough detail to avoid these types of errors. It is also recommended that package size and number of containers be filled in on the purchaser's copy of the DEA Form 222 when product is received, not just the number of containers. Additionally, it is recommended that DEA Forms 222 are distributed to the DEA as required and a log is used for all DEA Forms 222 for each registration that uses DEA order forms to ensure forms are not lost or stolen.

Finding No. 2:

Records are not being stored at each registered location, primarily executed DEA Forms 222 and required DEA inventories. It was indicated that all executed DEA Forms 222 between registrations (buildings) are filed in one central location.

Requirement: 21 CFR 1305.13 Procedure for filling DEA Forms 222

(d) The supplier must retain Copy 1 of the executed DEA Form 222 and forward Copy 2 to the DEA.

Requirement: 21 CFR 1305.17 Preservation of DEA Forms 222

(a) The purchaser must retain Copy 3 of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.

(b) The supplier must retain Copy 1 of each DEA Form 222 that it has filled, etc.

Requirement: 21 CFR 1304.04 Maintenance of records and inventories.

(b) All registrants that are authorized to maintain a central recordkeeping system shall be subject to the following conditions:

(1) The records to be maintained at the central record location shall not include executed order forms, prescriptions and/or inventories which shall be maintained at each registered location.

Recommendation:

All executed DEA Forms 222 must be filed at the registered location where the order was filled. Copy 3, the purchaser's copy, must be filed at the registered location where the product was received. The inventory of each registration must be retained on file at that location. Par Pharmaceutical must also assure that correct shipping and receiving forms for Schedule II, III, IV and V are filed at each location where product was shipped from and received at.

Copy 1 is retained by the Supplier
Copy 2 is forwarded to the DEA
Copy 3 is retained by the Purchaser

Finding No. 3:

Par Pharmaceutical used a DEA Form 236, Import Declaration, to import Oxandrolone, a Schedule IIIN controlled substance. The Declaration indicated that the import would be received at the [redacted] location; however, it is received at the [redacted] that actually holds the Importer Registration for Schedule IV.

Requirement: 21 CFR 1312.11 Requirement of authorization to import.

(b) No person shall import or cause to be imported any non-narcotic controlled substance listed in Schedule III, IV or V, excluding those described in paragraph (a) of this section, unless and until such person is properly registered under the Act (or exempt from registration) and has filed an import declaration to do so with the Administrator, pursuant to Sec. 1312.18 of this part.

Recommendation:

The imported Oxandrolone needs to be received at the facility which possesses the import registration, ensuring that the documentation is correct. If necessary for the drug to be sampled for testing, the sample would be properly transferred to a manufacturing registration for testing, using a form that lists all the required information. . Alternatively, the import registration at [redacted] can be modified to include Schedule IIIN, and all Import Declarations (DEA Form 236) be filled out for that registration for receipt at the [redacted] site. Transfer of the material to another registration would then follow internal procedures, including the use of an internal transfer form.

Another method for sampling would be for the importer to transfer a full container (as received from the supplier without opening) to the manufacturer for testing.

Finding No. 4:

Year-end reports for Narcotics (Morphine Sulfate, Oxycodone, Hydrocodone) have not been filed. Quota was received for Morphine Sulfate for 2009; other Schedule II narcotics were received as samples and were in inventory as of December 31, 2009. An incorrect conversion factor was noted for Morphine Sulfate (0.71 instead of 0.75). When year-end reports were filed for reportable psychotropics, the amount of product held in inventory as of December 31, 2009 incorrectly included material stored at the [redacted] facility under the distribution registration.

Requirement: 21 CFR 1304.21 (a) US Government / DEA Single Convention on Narcotic Drugs, 1961, Article 20

(a) Every registrant required to keep records pursuant to 1304.03 must maintain on a current basis a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her except that no registrant shall be required to maintain a perpetual inventory.

The Parties shall furnish to the Board for each of their territories, in the manner and form prescribed by the Board, statistical returns on forms supplied by it in respect of the following matters:

a) Production or manufacture of drugs;
b) Utilization of drugs for the manufacture of other drugs, of preparations in Schedule III and of substances not covered by this Convention, and utilization of poppy straw for the manufacture of drugs;
c) Consumption of drugs;
d) Imports and exports of drugs and poppy straw;
e) Seizures of drugs and disposal thereof;
f) Stocks of drugs as at 31 December of the year to which the returns relate; and
g) Ascertainable area of cultivation of the opium poppy.

Recommendation:

The year-end reports for all Schedule II narcotics need to be filed. Since Par Pharmaceuticals is registered as a central reporter, several problems were noted with the YERS program, the on line reporting system DEA uses to gather this data. DEA should be contacted to resolve the issue where the granted quota for Morphine Sulfate is not showing up on the YERS program. DEA should also explain how the two registrations are differentiated in the program. Par

Pharmaceuticals should assure the correct conversion factors are used for all salts. The year end reports for all reported psychotropics should be reviewed and revised if the inventory held as of December 31, 2009 included material from the distribution registration. It is also recommended that the drug codes on each manufacturing registration be checked, as it appeared that Morphine Sulfate (a bulk drug sample) was received on one manufacturing registration but it is uncertain if it had the drug code listed. It is further recommended that bulk drug samples for analytical evaluation be purchased under the analytical laboratory registration.

Finding No. 5:

During manufacturing and packaging, there is currently no designated observer identified in writing that monitors the process and assures that only required personnel enter and work in the area.

Requirement: 21 CFR 1301.73 Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.

(b) Manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access, which is under surveillance by an employee or employees designated in writing as responsible for the area. "Limited access" may be provided, in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated as responsible for the area may be engaged in the particular manufacturing operation being conducted: Provided, That he is able to provide continuous surveillance of the area in order that unauthorized persons may not enter or leave the area without his knowledge.

(c) During the production of controlled substances, the manufacturing areas shall be accessible to only those employees required for efficient operation. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through manufacturing areas during production of controlled substances, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

Recommendation:

A procedure needs to be put in place to identify in writing a designated observer for all controlled substance manufacturing activities. This person can be part of the operation, but must be able to monitor the area as described in the regulations stated above.

Finding No. 6:

It was indicated that Schedule II manufacturing activities are increasing, with the possibility of ramping up development work to produce scale up and submission batches. However, while the Schedule II vault is in one building, the processing area for these products is in another building. Each building holds its own DEA manufacturing registration. Quota (along with year-end reporting) would be required for each registration in order to move the material from one building to another. Additionally, each transfer would be required to be reported to ARCOS for both registrations (one sale, one purchase).

Requirement: 21 CFR 1301.73

"**Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.**

(a)All in-process substances shall be returned to the controlled substances storage area at the termination of the process. If the process is not terminated at the end of a workday (except where a continuous process or other normal manufacturing operation should not be interrupted), the processing area or tanks, vessels, bins or bulk containers containing such substances shall be securely locked, with adequate security for the area or building. If such security requires an alarm, such alarm, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant."

Recommendation:

It is recommended that:

a. The logistics of storing Schedule II in one building and processing in another be seriously evaluated and a Schedule II vault be installed so that there is a vault in both buildings.

b. Further consideration is required to take into account the possibility of storing Schedule II material overnight in the processing rooms, should this be required, due to any number of factors, including power outages, line breakdowns, end of shifts, etc. As per the regulations, the controlled substances would be required to meet the above requirements.

    * DEA approval should be obtained for the installation of any intended security for storage outside of a vault.

Finding No. 7:

According to the firm, a national background check is conducted by ADP Screening Services for all applicants recommended for hire; in addition, DEA checks are being done on all personnel who handle controlled substances; applicants recommended for hire undergo drug screening; and background checks are also conducted on TEMPS and Par Truck Drivers.

Requirements: 21 CFR 1301.90

"It is, therefore, assumed that the following questions will become a part of an employer's comprehensive employee screening program:

"Within the past five years, have you been convicted of a felony, or within the past two year, of any misdemeanor or are you presently formally charge with committing a criminal offense? (Do not include any traffic violation, juvenile offenses or military convictions, except by general court martial) If the answer is yes, furnish details of conviction, offense, location, date and sentence."

"In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details"
Requirement: 21 CFR 1301.91

"It is, therefore, the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of that employer."

Recommendation:

a. Any contractors and part time personnel that may have access to controlled substances should be subject to background investigations.

b. The cleaning service employees should also be subject to background investigations, but must not have access to controlled substances.

c. All employee background checks should be updated at a minimum of every five years.

d. Random drug testing should be instituted at the firm and for all employees (including management).

e. An SOP should be written to describe these activities.

Finding No. 8: Security

The current area used for packaging was observed to have gates on several sides that can be used to lock the area down during breaks, etc. when controlled substances are being packaged in that area. However, a double swinging door was noted along one wall, which allows access into the area.

Processing rooms were observed for granulation and compression of controlled substances. These rooms can be locked; however, there is no way to trace who is coming and going into these rooms.
Currently the guard force is present on site Monday through Friday, from 6 a.m. to 11 p.m.

Requirement: 21 CFR 1301.71 Security Requirements Generally

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances, etc.

Recommendation:

It is recommended that:

a. Card access readers should be installed on the doors used for accessing the packaging area and on the processing rooms used for granulation and compression.

b. The guard service be expanded at the [redacted] for 24/7 coverage.

Finding No. 8: SOM

There is no Suspicious Ordering Monitoring program in place.

Requirement: 21 CFR 1301.74(b)

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

Recommendation:

Although it was stated that sales are mainly to large wholesalers, a program must be instituted based on customers' sales volumes, seasonal fluctuations, etc., with a firm statistical analysis as the basis for such a program. It is further

recommended that the basis for conducting due diligence of new and existing customers and identifying, investigating and clearing or reporting suspicious orders be documented in an SOP.

Finding No. 9: Biennial Inventory

There are eight different DEA registrations betwee[redacted] Each DEA registration must have an individual DEA Biennial Inventory. If there are no controlled substances on hand for an individual registration, then a printed, dated, designated opening or closing and signed document stating that there is a zero inventory for the individual registration will suffice.

Requirement: 21 CFR 1304.11(b)

(b) Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacure, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section…

Recommendation:

It is recommended that the Biennial Inventory (once every two years) be conducted at least annually for all controlled substances in the control and possession of the individual DEA registrant. Each Biennial Inventory is to be labeled as the Biennial Inventory. The heading should contain the name, address, DEA registration number and business activity. The inventory must also list the date conducted and when conducted (opening or close of business). Schedule II controlled substances must be separate from the Schedule III, IV and V information. The inventory must list the names of the substances, the total quantity of the substance (bulk); the name of the substance and the quantity in each batch (in-process) and the name of the substance, strength, size and number of commercial containers for finished goods. All controlled substances must be counted, including samples, waste, rejects, and drugs for destruction. The person(s) conducting inventory should sign the inventory form, with a witness signature, and the Biennial Inventories must be stored at the registered location.

Any DEA registration that is less than two years old and for which no Biennial Inventory has been conducted must have an initial inventory, including a zero inventory, on file. Therefore, immediately conduct a DEA required inventory for that DEA registration. In addition, conduct a DEA biennial inventory for any inventory of a registrant that may not be complete.

Finding No. 10: Laboratory Records

Separate logbooks and usage sheets were observed in the analytical laboratory for sample receipt, sample sign out and usage. It was also observed where sign out for a Schedule II material was listed on the same page as Schedule III, IV and V samples. As

per the regulations, activity for Schedule I and II needs to remain separated out from Schedule III, IV and V.

Requirement: 21 CFR 1304.21 (a)

"Every registrant required to keep records pursuant to Section 1304.03 shall maintain on a current basis a complete and accurate record of each such substance … disposed of by him/her…"

Recommendation:

It is recommended that one logbook be instituted for Schedule II samples and another for Schedule III, IV and V samples, to include sample receipt from manufacturing or other registrations, sample sign out by chemist and all usage, with one sample per page in the logbook.

Finding No. 11: Destruction Records

DEA Forms 41 are being filled out by Par personnel to facilitate the transfer and destruction of material via their reverse distributor. Abbreviations are being used for a number of controlled substance samples. It is unclear which materials these are.

Requirement: 21 CFR 1304.21 (a)

"Every registrant required to keep records pursuant to Section 1304.03 shall maintain on a current basis a complete and accurate record of each such substance … disposed of by him/her…"

Recommendation:

It is recommended that the practice of filling out the DEA Forms 41 for the reverse distributor be discontinued. Material for destruction should be captured using an Excel spreadsheet, to include the full product name and strength. Schedule II material needs to be collected and stored separately from Schedule III, IV and V. Ensure a distribution record that lists all the required information is utilized for all material distributed/forwarded to a reverse distributor, to include name, address and DEA registration number for both parties. An SOP is currently in place to describe a destruction procedure, but needs to be updated and made into a global document with more detailed information on the current process.

- Schedule II – DEA Form 222 and a distribution record
- Schedule III, IV and V – A distribution record

Finding No. 12: Registration Verification

The firm obtains a copy of each registration and has that on file. They do not do a verification check for each order; but will ship up to the day before a DEA registration expires.

Requirement: 21 CFR 1301.74 (a)

"Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance."

Recommendation:

It is recommended that:

a. A 5-10 day no ship period be instituted on an expiring DEA registration.

b. Periodic checks on all registrations be done via the DEA website, registration verification program.

c. Subscribe to the DEA Registrant Listing.

Finding No. 13: ARCOS Reporting

Incorrect usage of the Insert transaction code (I) was noted. This code is only used for late transactions that fall outside of the dates for the current reporting period. Year-end inventories of Schedule II material (Morphine Sulfate, etc.) was not reported at 4Q2009. These inventories need to be inserted as late transactions (I) for the current reporting period (2Q2010). Par must assure the transaction code is "3", year-end inventory, and the date is 12/31/2009. All Schedule II material in inventory should be tracked back to the DEA Form 222 that was used for purchasing, to ensure the correct registration is being referenced.

The transfer of laboratory samples to the analytical registration was not reported for 4Q2009. These sales need to be inserted as late transactions, with the actual date of transfer used as the transaction date. Laboratory samples transferred between registrations will always be captured as Sales for all ARCOS reportable materials.

Requirement: 21 CFR 1304.21 (a)

"Every registrant required to keep records pursuant to Section 1304.03 shall maintain on a current basis a complete and accurate record of each such substance … disposed of by him/her…"

Recommendation:

Implement corrections as noted above, a process needs to be put into place to collect data from all manufactured batches to report unrecovered waste (N) and recovered (collected) waste (W) for all Schedule II material and Schedule III narcotics; assure NDC numbers are assigned for all ARCOS reportable materials (in process and finished dosage forms) as soon as R&D activities are initiated and these NDC numbers need to be submitted to DEA for inclusion in the NDC dictionary.

An SOP on the ARCOS process should be written to describe this process in detail due to the numerous registrations in place and the transactions that occur.

OTHER ISSUES

1. Distribution

Shipping cartons were observed with an outside sleeve that contains a packing list of the items inside. It is recommended that this practice be discontinued, with the packing slip inserted into the carton. For those customers who require an outside packing slip, it is recommended that the product name and strength not be used and the NDC code be referenced instead.

2. Quotas

Par should ensure that adequate information is included in letters to DEA that accompany DEA Forms 250, application for quotas. This will be crucial moving forward if and when Schedule II material is transferred from one registration (building) to another during the manufacturing process. Assure drug codes are requested prior to sending in a DEA Form 250 for quota application for a new Schedule II material.

It is recommended an SOP be put into place to describe the quota process in detail, along with Year End Reporting requirements, and how data is collected and processed for year-end reconciliation.

3. Controlled Substance Storage

Samples in the vault were observed to be stored in brown paper bags, or plastic bags with loose inventory sheets inside the bags. It is recommended that sealable drums or totes be used for the storage of all controlled substances. Inventory and usage records should be maintained in bound logbooks. Numbered seals should be used on all drums and totes whenever material is added to or removed from each container. A cross check of the numbered seal will readily indicate if the container has been breached without a reasonable explanation.

It was indicated that laboratory chemists lock up controlled substances during the day when not in use. It was observed that this practice is not universally followed, and is not incorporated into the laboratory SOP. It is recommended that the SOP be updated to include this process and all chemists be trained and instructed to lock up all controlled substances under their care during the day.

4. DEA Training

Training for all employees who handle controlled substances should be performed yearly for all pertinent SOPs, similar to the procedure used for GMP training.

5. SOPs

All SOPs currently in place should be reviewed, updated and globalized to include activities across the entire site, not just R&D. In addition to those SOPs previously recommended, the following SOPs should be written and/or rewritten:

Loss/Theft of Controlled Substances
DEA Compliance Audits
Suspicious Ordering Monitoring
How to Handle a DEA Inspection
Hiring
Record Keeping Requirements
Conducting DEA Required Inventories.
Distribution to a DEA Registered Reverse Distributor
ARCOS
Security
Quotas
Laboratory Storage

QUALIFICATIONS:

1. The foregoing analysis reflects our observations and recommendations based on information and individuals made available to us by the company during the review period. A review of additional records and interviews with additional representatives could result in additional issues and recommendations.

2. The foregoing recommendations represent our best professional judgment based on our knowledge of the DEA regulations and our experience with them. Many of the requirements of the DEA and regulations there are subject to interpretation and are subjective. Implementation of these recommendations does not guarantee that DEA would not find any violations; the recommendations must be considered with this in mind.

3. No analysis has been provided as to the consequences of current or prior violations of DEA regulations, if any that may be noted in this report.

